

REMARKS

Status of Claims

Claims 1-34, 43-45, and 51 stand rejected as allegedly anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,251,407 to Ganne ("Ganne"). Applicants respectfully submit added claims 54-56. Applicants respectfully submit that no new matter has been added by the above amendments. Support for the added independent claims 54-56 is found at least at page 2, lines 2-12 of the specification.

Reply to Office Action Remark on Priority

Applicants respectfully submit an amendment to the specification to address the Office Action's request for an update to the cross reference section of the application. Applicants respectfully note that this amendment refers to the parent application by application and patent numbers.

Reply to Claim Rejections Under 35 U.S.C. § 102(e)

Claims 1-34, 43-45, and 51 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,251,407 to Ganne ("Ganne").

In the Office Action, the Examiner asserts that Ganne anticipates the claims because the reference allegedly discloses a composition having the same components. In particular, the Examiner alleges that "Ganne teaches . . . an aqueous solution with a water soluble salt of aluminum . . . where the water soluble metal is pyruvic acid and gluconate compound . . . and HLB number between 6 and 14." Office Action page 3. The Office Action also alleges that "Ganne teaches compositions comprising ethoxylated/alkoxylated derivatives of corn oil . . . where the hexol is a sorbitol . . . where the fatty acids comprise acryl radicals of 12-22 carbon atoms . . . and a compound of the formula $R_1-O-(G)_x-H$ this includes polymerization of between 1 and 3 . . . for injection including intramuscular and subcutaneous [sic] (parenteral)." Office Action pages 3-4.

To anticipate a claim, a cited reference must teach each and every element of the claim. See M.P.E.P. § 2131, *citing e.g., Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”). Applicants respectfully traverse this rejection because Ganne fails to teach all of the recited claim elements.

Ganne discloses a composition with “(i) at least one antigen or at least one in vivo generator of a compound comprising an amino acid sequence and (ii) at least one adjuvant comprising at least one pharmaceutically acceptable and water-soluble salt of an organic anion and a metal cation.” Ganne abstract. Ganne does not teach the frozen storage of compositions.

In contrast, claim 1 of the present application recites in pertinent part “the at least one antigenic medium and the at least one adjuvant each comprise one or more phases which are distinct from each other when the composition is in a solid state.” Ganne does not disclose “the at least one antigenic medium and the at least one adjuvant each comprise one or more phases which are distinct from each other when the composition is in a solid state.” In fact, Ganne does not disclose freezing compositions for storage or disclose storage of a compound in the solid phase. Ganne only discloses that “[t]he emulsion must be stable preferably for at least 12 months when it is stored at 4°C,” but this does not disclose storage of compounds in a frozen form. Ganne col. 3, ll. 59-61. Ganne therefore does not disclose storage of a compound in “phases which are distinct from each other when the composition is in a solid state,” as found in claim 1, as Ganne does not at all disclose freezing compositions for storage.

Further, the Examiner disregards the functional elements of the claims in asserting that the recited elements of claim 1 “when . . . in a solid state” and “when the temperature” are “intended uses or conditions that are not required by the claim.” Office Action, page 3. Contrary to the Examiner’s assertions, the recited functional elements of the claims sufficiently describe the claimed invention and further distinguish it over the cited reference.

It is well established that a composition may be defined by its function. According to the PTO's regulations, "[a] functional limitation is an attempt to define something by what it does, rather than by what it is . . . [t]here is nothing inherently wrong with defining some part of an invention in functional terms." M.P.E.P. § 2173.05(g). "A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." M.P.E.P. § 2173.05(g). For instance, the term "surfactant" does not describe a specific chemical structure, but rather describes a class of compounds according to a property of those compounds. There is no question, however, that such a term conveys meaning to one of ordinary skill in the art, and is therefore a proper functional limitation.

Although the Office Action alleges that the terms "when. . . in a solid state" and "when the temperature" are not required by the claim, these terms are proper functional elements of the claim. One element of claim 1 is that "the composition is in the liquid state when its temperature is greater than or equal to 4°C." Many compounds have a freezing point which is above 4°C. These compounds would not meet this element, because they would not be "in the liquid state when its temperature is greater than or equal to 4°C." Ample structure for this element may be found in the specification of the application. For example, the specification at p.17, l.9 describes a process for freezing a composition. The specification at pp. 21-31 describes several tests conducted on frozen and unfrozen compositions. Accordingly, the proper functional elements of the claims further define the claimed composition over that described by Ganne.

In view of at least the foregoing, Ganne does not disclose "each and every element as set forth in the claim," and therefore does not anticipate. Applicants respectfully request withdrawal of the rejection of claim 1, as well as claims 2-34, 43-45, and 51 which depend from independent claim 1, and an indication that the claims are allowable.

CONCLUSION

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their counsel to resolve such issues and place all claims in condition for allowance. It is believed only a fee in the amount of \$450.00 for a two month extension of time is required with this response. However, the Commissioner is hereby authorized to charge fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required now or hereafter, or credit any overpayment, to Deposit Account No. 50-0206.

Respectfully submitted,

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